

EPA REGISTRATION NUMBER 56783-1- Vol. 2

PROCESSING REQUEST

Reg # 36783-1

Decision # 53/676

Description: Graphics & marketing claims

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☒ Dated: 8-25-17

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Angela Hollis

Division: RD

Phone: 347-0216

Date: 8-28-17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 25, 2017

Sharon M. Johnston
Regulatory Consultant
EcoHealth, Inc
56 Hawes Street
Brookline, MA 02446

Subject: Notification per PRN 98-10 – Directions for use graphics, marketing claim and guarantee statements
Product Name: DAMMINIX
EPA Registration Number: 56783-1
Application Date: 7/21/2017
Decision Number: 531678

Dear Ms. Johnston:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

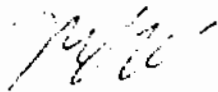
The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

Page 2 of 2
EPA Reg. No. 56783-1
Decision No. 531678



Michael Wagman, Acting Product Manager 4
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

NOTIFICATION

56783-1

This notification is submitted to inform you of any changes, other than those reported in the Agency's previous notification, including the Agency's knowledge of the notification's accuracy.

08/25/2017

56783-1: Page 1 of 3
EPA Notification: 07/21/2017

DAMMINIX®

[A TICK TOXICANT

- As an aid in the control of ticks (that may carry Lyme Disease) [that infest mice and nests of mice found around yards, play areas, parks, brush, paths and in woodlands].
- For Treatment Around Yards and Wooded Lots
- Easy to Use.
- Apply [twice a year] [2x a year] [once in the spring and once in the summer].
- Place in Brush, Woodpiles, Rock Walls and Flower Beds.
- ~~24 tubes treat approximately 22,000 sq. ft.~~
- 6 tubes treat approximately 5,500 sq. ft.
- x tubes treat approximately x sq. ft. [of mouse habitat][including] [brush-covered areas, woodlands, flower beds, woodpiles, rock walls] [per application] (Note to Reviewer: application rate remains the same but number of tubes and coverage area can be adjusted based on package size)
- Place tubes no greater than 10 yards apart from each other.]

Active Ingredient:

Permethrin* 7.4%

Other Ingredients: 92.6%

Total 100.00%

*Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

EPA Reg. No. 56783-1

EPA Est. No.

Keep Out of Reach of Children

CAUTION

First Aid

If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Immediately rinse skin with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may call 1-800-222-1222 for emergency medical treatment information.

See side [back] panel for additional precautions.

EcoHealth, Inc.
56 Hawes Street
Brookline, MA 02446
(617) 742-2400

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

Physical or Chemical Hazards

Combustible. Do not use or store near excess heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

{Alternate text and graphics to provide clarification to the user on how the product works}

[A: [How Tick Control Tubes Work] [How it Works]



1. Ticks feed on mice.



2. Tick Control Tubes are filled with [cotton][material] treated with permethrin insecticide.



3. Mice collect the treated [material] [cotton] and use it to line their nests.



4. Ticks feeding on the mice are exposed to the [material treated with] permethrin insecticide.]

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. Do not exceed the maximum distance of 10 yards between tubes in any direction. Limit treatment areas to those areas inhabited by mice, and need not include mown lawns or open grasslands. Position tubes so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, apply tubes to all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected.

FOR TREATMENT OF WOODLOTS: Place tubes in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed. The tubes and unused cotton are biodegradable and may be left in the application site.

Storage and Disposal

Do not contaminate water, food or feed by storage.

Pesticide Storage: Store at room temperature in an area inaccessible to children and pets.

Pesticide Disposal and Container Handling: If empty: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

Net Contents: x tick control tubes at x oz. (x grams) each

Total: x oz. (x grams)

[100% Satisfaction Guaranteed. At EcoHealth, Inc., we stand behind our products and our quality. If you are not completely satisfied with your EcoHealth, Inc. purchase, you may return it to us for replacement or refund.]

RegGuide

July 21, 2017

Document Processing Desk (NOTIF)
Invertebrate-Vertebrate Branch I
Registration Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900; One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Kable Bo Davis
Product Manager 03

SUBJECT: Submission of Label Notification Per PR Notice 98-10
Damminix; EPA Reg. No. 56783-1

Dear Mr. Davis:

Enclosed, please find a marked copy of the above-subject product label. Specific changes include:

- 1) Addition of alternate marketing bullets consistent with current label language.
- 2) Addition of an alternate "How It Works" section to clarify what the product does for the end user.
- 3) Addition of an alternate guarantee statement.

If you have any questions or need additional information, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston
Regulatory Consultant

Enclosures

cc: A. Ganak; EcoHealth

Sharon M. Johnston, Esq.
509 Tower Valley Drive
Hillsboro, MO 63050

Tel: 636-942-2583
Fax: 636-948-9720
e-mail: Johnston@RegGuide.net



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-1	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Damminix	PM# 03	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Notification of Alternate Marketing Bullets, Guarantee Language, Addition of "How It Works" section including graphics and text to provide clarification to the end-user.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted				<input checked="" type="checkbox"/> Glass	<input type="checkbox"/> Paper
If "Yes" Unit Packaging wgt. 0.16 oz	No. per container 6-24	If "Yes" Package wgt.	No. per container	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.96 - 3.84 oz		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed directly on package			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sharon M. Johnston	Title Regulatory Consultant	Telephone No. (Include Area Code) (636) 942-2583
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
Signature 	3. Title Regulatory Consultant	
Typed Name Sharon M. Johnston	5. Date July 21, 2017	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 17, 2017

Sharon M. Johnston, Esq.
Agent for EcoHealth, Inc.
c/o RegGuide
509 Tower Valley Dr.
Hillsboro, MO 63050

Subject: PRIA Label and CSF Amendment – Addition of alternate CSF #2 and of a
Physical or Chemical Hazards section.
Product Name: Damminix
EPA Registration Number: 56783-1
Application Date: 10/6/2016
Decision Number: 522505

Dear Ms. Johnston:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 06/23/2015
- Alternate CSF 1 dated 06/23/2015
- Alternate CSF 2 dated 10/6/2016

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the

website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jennifer Gaines by phone at (703) 305-5967, or via email at gaines.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, loopy oval shape.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

DAMMINIX®

[A TICK TOXICANT

As an aid in the control of ticks (that may carry Lyme Disease) [that infest mice and nests of mice found around yards, play areas, parks, brush, paths and in woodlands].

Easy to Use.

Apply once in the spring and once in the summer.
Place in Brush, Woodpiles, Rock Walls and Flower Beds.

24 tubes treats approximately 22,000 sq. ft.
6 tubes treat 5,500 sq. ft.
Place tubes no greater than 10 yards apart from each other.]

ACCEPTED

01/17/2017

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 56783-1

Active Ingredient:

Permethrin* 7.4%

Other Ingredients: 92.6%

Total 100.00%

*Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

EPA Reg. No. 56783-1 EPA Est. No.

Keep Out of Reach of Children
CAUTION

First Aid

If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
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If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Immediately rinse skin with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may call 1-800-222-1222 for emergency medical treatment information.

See side [back] panel for additional precautions.

EcoHealth, Inc.
56 Hawes Street
Brookline, MA 02446
(617) 742-2400

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

Physical or Chemical Hazards

Combustible. Do not use or store near excess heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. Do not exceed the maximum distance of 10 yards between tubes in any direction. Limit treatment areas to those areas inhabited by mice, and need not include mown lawns or open grasslands. Position tubes so that mice have access to the open ends. Product works best if not covered by leaves or other material.

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Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed. The tubes and unused cotton are biodegradable and may be left in the application site.

Storage and Disposal

Do not contaminate water, food or feed by storage.

Pesticide Storage: Store at room temperature in an area inaccessible to children and pets.

Pesticide Disposal and Container Handling: If empty: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

Net Contents: x tick control tubes at x oz. (x grams) each
Total: x oz. (x grams)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

FILE

- Contains Confidential Business Information -

DP BARCODE No.: 436683; FILE SYMBOL No.: 56783-1; PRODUCT NAME: Damminix;
DECISION No.: 522505; PC Code(s): 109701; ACTION CODE: R340; FOOD Use: NO

DATE OUT: January 9, 2017

SUBJECT: End Use Product Chemistry Review – *Damminix*
-Amendment to Add Alternate #2 Formulation

FROM: María I. Rodríguez, Chemist
Product Chemistry Reviewer
CITAB/RD (7505P)

María I. Rodríguez
January 9, 2017

THROUGH: Shyam Mathur, Ph. D.
Product Chemistry Team Leader
CITAB/RD (7505P)

SRM 01/9/17

TO: Jennifer Gaines/Kable Davis, RM #3
IV #1/RD (7505P)

INTRODUCTION:

The CITAB (Chemistry) has been asked to determine the acceptability of supporting Product Chemistry data submitted with this application.

Registrant: RegGuide, Agent for EcoHealth, Inc

Application Date: October 6, 2016

Proposed Product: Insecticide containing permethrin to control of ticks as listed on the proposed label

Supporting Data: Alternate #2 CSF, Data Matrix, Proposed label, Documents with MRID Nos 500828-01, and -02

45/90-Day Completeness Screen: 12-06-2016 (MIRodriguez); NO Deficiencies Listed

SUMMARY OF FINDINGS:

1. Name(s) of Active Ingredient(s): 7.4% permethrin
2. Has the registrant claimed substantial similarity to a registered product? ☐ Yes; ☒ No
3. All of the source materials of the active ingredients are derived from registered sources: ☒ Yes; ☐ No
-EPA Reg No [REDACTED]
4. All inert ingredients have been screened by CITAB (Inerts) and found to be approved for the proposed labeled use(s): ☒ Yes; ☐ No
- Non-food (JG, 11-10-2016)
5. Confidential Statement(s) of Formula (CSFs):
☒ Proposed Alternate (ALT) #2 CSF: Dated: 10-06-2016

6. Product label:

- a. Ingredient statement: Nominal concentration (NC) of AIs listed on CSF concur with product label (PR Notice 91-2): ☒ Yes; ☐ No

Is the sub statement in compliance with PR Notice 97-6 (inert ingredients vs other ingredients)?
☒ Yes; ☐ No

Metallic equivalent: ☐ Yes; ☐ No; ☒ NA
Soluble arsenic: ☐ Yes; ☐ No; ☒ NA
Isomeric ratios: ☐ Yes; ☐ No; ☒ NA
Acid Equivalent: ☐ Yes; ☐ No; ☒ NA

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA
Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA
Sodium nitrate/Sodium Nitrite: ☐ Yes; ☐ No; ☒ NA

- c. Physical-chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown? ☒ Yes; ☐ No
-See Finding #9 below for flammability information to be added to the label

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
☐ Yes; ☐ No; ☒ NA

- d. Label requires an additional Storage and Disposal statement: ☐ Yes; ☒ No

7. Group A: Product Chemistry Data – Product Identity, Composition, and Analysis

-NOTE: Data from SAlekseyev to BAdler on 04-24-2012 and 05-07-2013 unless otherwise indicated

Guideline Number	Study Title		Data Submitted		CITAB's Assessment of CHEMISTRY Data	MRID Number Cited
			Yes	No		
830.1550	Product Identity & Composition		X		A	500828-01
830.1600	Description of materials used to produce the product		X		A	Alternate #2 CSF 500828-01
830.1620	Description of the production process		----	----	NA Batch - EP	NA
830.1650	Description of formulation process		X		A	500828-01
830.1670	Discussion on the formation of impurities		X		A	500828-01
830.1700	Preliminary analysis		----	----	NA Batch - EP	NA
830.1750	Certified limits (158.350)	Standard certified limits	X		A	500828-01 Alternate #2 CSF
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	----

A = Acceptable; N = Not Acceptable; G = Data Gap; W = Waiver request; NA = Not applicable;
 I = In Progress; U = Upgradeable

8. Group B: Product Chemistry Data – Physical and Chemical Characteristics

-NOTE: Data from SAlekseyev to BAdler on 04-24-2012 and 05-07-2013 unless otherwise indicated

Guideline Number	Study Title	Value or Qualitative Description	CITAB's Assessment of CHEMISTRY Data	MRID Number Cited
830.6302	Color	White	A	----
830.6303	Physical State	Solid	A	----
830.6304	Odor	None	A	----
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	NA	NA	----
830.6314	Oxidation/reduction	NA	NA	----
830.6315	Flammability	NA	NA	----
830.6316	Explosibility	NA	NA	----
830.6317	Storage stability	Stable for 2 weeks @ 54 °C	A	----
830.6319	Miscibility	NA	NA	----
830.6320	Corrosion characteristics	Stable for 2 weeks @ 54 °C	A	----
830.6321	Dielectric breakdown voltage	NA	NA	----
830.7000	pH	NA	NA	----
830.7100	Viscosity	NA	NA	----
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	1.5 per cotton ball	A	Alternate #2 CSF

A = Acceptable; N = Not Acceptable; G = Data Gap; W = Waiver request; NA = Not applicable;
 I = In Progress; U = Upgradeable

8. Additional: Product Chemistry Data – Physical and Chemical Characteristics

Flammability Test: current and proposed alternate formulations to determine difference (if any)

Qualitative Description: Proposed alternate formulation has a faster burn time. The registrant is proposing to add a statement under "Physical and Chemical Hazards" section that would read as follows:

"Combustible: Do not use or store near excess heat or open flame."

The registrant indicated this should apply to all formulations.

CITAB's Assessment: CITAB (Chemistry) is in agreement with the registrant.

C. CONCLUSIONS:

CITAB has reviewed the Product Chemistry data submitted and has concluded that:

A. Substantial Similarity to the Cited Product from Product Chemistry View Point

- ☐ Similar to cited product
- ☐ Not similar to cited product
- ☐ Identical to the cited product in chemical composition
- ☐ Not identical
- ☒ Not applicable

B. Confidential Statement(s) of Formula

Alternate #2 CSF

- ☒ Acceptable
- ☐ Not Acceptable
- ☐ Not Applicable

C. Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of Guideline(s): *(provide Guideline No & explain)*
- ☐ Not required
- ☐ Data cited

D. Group B Product Chemistry Data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of Guideline(s): *(provide Guideline No & explain)*
- ☐ Not required
- ☐ Data cited

E. Product Label/Draft Label

Recommendations – Yes ☒; No ☐

-As per flammability tests results, it is recommended that the following statement be added under the "Physical and Chemical Hazards" section of the label:

"Combustible: Do not use or store near excess heat or open flame."

It is under your purview that the label is revised/amended as appropriate.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

- Contains Confidential Business Information -

DP BARCODE No.: 436683; **FILE SYMBOL No.:** 56783-1 (Screen); **PRODUCT NAME:** Damminix;
DECISION No.: 522505; **PC Code(s):** 109701; **ACTION CODE:** R340; **FOOD Use:** NO

DATE OUT: December 6, 2016

SUBJECT: 45/90-Day Completeness Screen Results for End-Use Product "Damminix."
-Amendment to Add Alternate #2 Formulation

FROM: Maria I. Rodriguez, Product Chemistry Reviewer, CITAB/RD (7505P)

TO: Jennifer Gaines/Laura Bacon, RM #4, IV#4/RD (7505P)

Company Name: RegGuide, Agent for EcoHealth, Inc
Active Ingredient(s): Permethrin
MRID No(s): 500828-01, -02

CONCLUSIONS:

Deficiencies: NO

(If there are deficiencies, they are indicated below each heading as "Note 1, Note 2, etc.")

Group A Data:

- Submitted (see above)
- Cited in Data Matrix (dated 10-06-2016)

Group B Data:

- Submitted (see above)
- Cited in Data Matrix (dated 10-06-2016)

CSF(s): Submitted

-Alternate #2 (dated 10-06-2016)

DRAFT Product Label: Submitted

Note to PM Team Reviewer: If deficiencies are found in the screen results, please inform the Registrant ("10-Day Letter") and provide me with the corrected deficiencies. I will attach the new information to the original bean sheet if the data package is still in CITAB. A new bean sheet will be required if the original bean sheet has been closed by CITAB.

50082800

RegGuide

October 6, 2016

Document Processing Desk (REGFEE)
 Invertebrate-Vertebrate Branch I
 Registration Division (7504P)
 Office of Pesticide Programs
 US Environmental Protection Agency
 Room S-4900; One Potomac Yard
 2777 S. Crystal Drive
 Arlington, VA 22202

ATTN: Laura Bacon
 Product Manager 4

SUBJECT: Application for Pesticide Registration Amendment
 R340 – Submission of Product Chemistry Data and Corresponding Label Change
 Damminix; EPA Reg. No. 56783-1

Dear Ms. Bacon:

Enclosed, please find the following materials in support of the application for amendment of the above-subject product on behalf of EcoHealth, Inc.:

- 1) Application for 75% reduction of PRIA III fee and supporting documents
- 2) Copy of fee payment receipt
- 3) Application for Pesticide Registration Amendment
- 4) Formulators Exemption Statement
- 5) Confidential Statement of Formula Alternate #2
- 6) Certification with Respect to Citation of Data
- 7) Data Matrix
- 8) Draft Labeling (5 copies)
- 9) Data Volumes 1 & 2 (3 copies)

A transmittal document is attached as page 3 of this letter.

We are requesting the addition of an alternate formulation process and Confidential Statement of Formula. The current Basic and Alt. #1 CSF's remain unchanged. Data volume 1 of 2 includes a description of the alternate formulation process. Flammability testing was conducted on both the current and the proposed alternate formulations to determine if the formulations were significantly different. These data can be found in data volume 2 of 2. Although the alternate formulation process did result in a faster burn time of the material, both formulations did in fact burn when exposed to open flame. Therefore, we believe the addition of a Physical or Chemical Hazards section is appropriate regardless of which formulation process is used.

We are also submitting a revised label with the addition of the Physical and Chemical Hazards section as noted above. And we request the addition of several alternate marketing bullet points consistent with the directions for use on the current approved label.

Page 2

Sincerely,

Enclosures

cc: A. Ganak; EcoHealth

A collection of 15 small, stylized line drawings of various insects, including beetles, flies, and bees, arranged in a grid-like fashion.

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

EcoHealth, Inc.
56 Hawes Street
Brookline, MA 02446

2. Regulatory Action in Support of Which This Package is Submitted

Application for Pesticide Registration Amendment (R340)
Damminix; EPA Reg. No.: 56783-1

3. Transmittal Date

October 6, 2016

4. List of Submitted Studies:

<u>MRID No.</u>	<u>Volume No.</u>	<u>OPPTS Guideline No.</u>	<u>Study Title</u>
<u>50082801</u>	1 of 2	830.1600, 1650 & 1750	Group A Product Chemistry of Damminix (EPA Reg. No. 56783-1) Alternate Formulation Process
<u>50082802</u>	2 of 2	830.6315	Product Chemistry Relative Flammability and Combustibility of Zecken Rollen Tick Tubes

Company Official: Sharon M. Johnston
Regulatory Consultant
Agent for EcoHealth, Inc.

Phone: (636) 942-2583

Signature: 

Company Name: EcoHealth, Inc.

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10-7-16

Experts In-Processing Signature: B.B. Date 10-13-16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>56783-1</u>		EPA Receipt Date: <u>10-7-16</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass
- Required forms are complete

Invests: Pass
- Invests approved for Non-food use

PRN 11-3: Pass
MRID-500828

AN 10/14/16

Overall Status: Pass



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

EcoHealth, Inc.
56 Hawes St.
Brookline, MA 02446

EPA File Symbol/Registration Number

56783-1

Product Name

Damminix

Date of Confidential Statement of Formula (EPA Form 8570-4)

October 6, 2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Permethrin

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

- (3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Permethrin		
Permethrin		
Permethrin		

Product ingredient source information may be entitled to confidential treatment

Signature**Name and Title**

Sharon M. Johnston / Regulatory Consultant

Date

October 6, 2016



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number EcoHealth, Inc., 55 Hawes St., Brookline, MA 02446 TEL: (636) 942-2583	EPA Registration Number/File Symbol 56783-1
Active Ingredient(s) and/or representative test compound(s) Permethrin	Date October 6, 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Non-Food, Domestic Outdoor	Product Name Damminix

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 10-06-2016	Typed or Printed Name and Title Sharon M. Johnston / Regulatory Consultant
---------------	--------------------	---

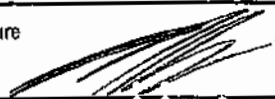


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date October 6, 2016			EPA Reg No./File Symbol 56783-1		Page 1 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446			Product Damminix		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	48085301	EcoHealth	OWN	
61-2/830.1600	Description of Beginning Materials	48085301	EcoHealth	OWN	
61-2/830.1600	Description of Beginning Materials	Vol. 1 of 2	EcoHealth	OWN	
61-2/830.1650	Description of Formulation Process	48085301	EcoHealth	OWN	
61-2/830.1650	Description of Formulation Process	Vol. 1 of 2	EcoHealth	OWN	
61-3/830.1670	Discussion of Formation of Impurities	48085301	EcoHealth	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
62-2/830.1750	Certification of Ingredient Limits	48085301	EcoHealth	OWN	
62-2/830.1750	Certification of Ingredient Limits	Vol. 1 of 2	EcoHealth	OWN	
62-3/830.1800	Analytical Method to Verify Certified Limits	48085301	EcoHealth	OWN	
63-2/830.6302	Color	00164297	EcoHealth	OWN	
63-3/830.6303	Physical State	00164297	EcoHealth	OWN	
63-4/830.6304	Odor	00164297	EcoHealth	OWN	
63-5/830.7200	Melting Point				NA - EP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 10-06-2016




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date October 6, 2016		EPA Reg No./File Symbol 56783-1		Page 2 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product Damminix			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-6/830.7220	Boiling Point				NA - EP
63-7/830.7300	Density, Bulk Density or Specific Gravity	00164297	EcoHealth	OWN	
63-8/830.7840 & 830.7860	Solubility				NA - EP
63-9/830.7950	Vapor Pressure				NA - EP
63-10/830.7370	Dissociation Constant				NA - EP
63-11/830.7570	Octanol Water Partition Coefficient				NA - EP
63-12/830.7000	pH				NA - Not dispersible with water
63-13/830.6313	Stability				NA - EP
63-14/830.6314	Oxidizing/Reducing Action				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	Vol. 2 of 2	EcoHealth	OWN	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6317	Storage Stability	49081801	EcoHealth	OWN	
63-18/830.7100	Viscosity				NA - solid
63-19/830.6319	Miscibility				NA - Not an EC
63-20/830.5320	Corrosion Characteristics	48719802	EcoHealth	OWN	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 10-06-2016




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date October 6, 2016		EPA Reg No./File Symbol 56763-1		Page 3 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product Damminix			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	43799701	MGK	OLD	
81-2/870.1200	Acute Dermal Toxicity	43799702	MGK	OLD	
81-3/870.1300	Acute Inhalation Toxicity	43799703	MGK	OLD	
81-4/870.2400	Primary Eye Irritation	47879901	EcoHealth	OWN	
81-5/870.2500	Primary Dermal Irritation	43799705	MGK	OLD	
81-6/870.2600	Dermal Sensitization	43893801	MGK	OLD	
95-11/810.3500	Efficacy data - ticks	00164298	EcoHealth	OWN	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 10-06-2016

29



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 12, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-522505
EPA File Symbol or Registration Number: 56783-1
Product Name: DAMMINIX
EPA Receipt Date: 07-Oct-2016
EPA Company Number: 56783
Company Name: ECOHEALTH, INC.

SHARON M. JOHNSTON
REGGUIDE
REPRESENTING ECOHEALTH, INC.
509 TOWER VALLEY DRIVE
HILLSBORO, MO 63050

SUBJECT: Receipt of Amendment and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your amendment, 75% small business waiver request, and certification of payment. If you submitted data with this amendment, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "J. J. [unclear]".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{993200g~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ✓

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 4

Receipt No.

S-

993200

EPA File Symbol/Reg. No.

56783-1

Pin-Punch Date:

10/7/2016

This item is NOT subject to FFS action.

Action Code:

Requested: R340

Granted: R340

Amount Due: \$ 3988.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐

Uncleared Inert in Product

Reviewer: [Signature]

Date: 10/12/16

Remarks:

S: 993200

Milestone Email:

Regulatory Type: Product Registration - Section 3



Resubmission: ☐ Yes ☒ No

Fee For Service: ☐ Yes ☒ No

Billable: ☒ Yes ☐ No



Print Letter

Enter More Information

Tracking

Application Type: Amendment



Company: 56783 ECOHEALTH, INC.

Risk Manager: Registration Division, Risk Management Team 4



Product #: 56783-1

Product Name: DAMMINIX

Override:

Me Too
Section3:

Me Too Product
Name:

Application Date: 06-Oct-2016



OPP Rec'd Date: 07-Oct-2016



Front End Date: 07-Oct-2016



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track:



New Ingredient:



Receipt Description:

AMENDMENT WITH STUDIES/FEE WAIVER

Receipt Content

Study

CSF

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A:



Signature Date:

Form B:



Signature Date:



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-1	2. EPA Product Manager Laura Bacon	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Damminix	PM# 4	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 56 Hawes St. Brookline, MA 02446 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

R340 Action - Submission of Alternate Formulation Process and Supporting Product Chemistry Data

e-mail: Johnston@RegGuide.net

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.16 oz	No. per container 6 - 24	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.95 - 3.81 oz		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed directly on package			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Sharon M. Johnston		Title Regulatory Consultant		Telephone No. (Include Area Code) 636-942-2583	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stampcd)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Sharon M. Johnston		5. Date October 6, 2016			



Receipt

Your payment is submitted

Pay.gov Tracking ID: 25UAC2H3

Agency Tracking ID: 75105813828

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Bank account (ACH)

Payment Amount: \$997.00

Transaction Date: 10/06/2016 04:11:00 PM EDT

Payment Date: 10/07/2016

Registration Number: 56783-1

Company Name: EcoHealth, Inc.

Company Number: 56783

Action Code: R340

Account Information

Account Holder Name: Sharon M Johnston

Routing Number: 081503607

Account Number: *****3201

Email Confirmation Receipt

No confirmation email was provided during the creation of this transaction.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 15, 2016

Sharon M. Johnston
Regulatory Consultant
EcoHealth, Inc
56 Hawes Street
Brookline, MA 02446

Subject: Notification per PRN 98-10 – ABNs
Product Name: DAMMINIX
EPA Registration Number: 56783-1
Application Date: 10/12/2016
Decision Number: 522661

Dear Ms. Johnston:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand names "Damminix Tick Control System" and "Damminix Tick Defense System" have been added to the product record.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "K B Davis", enclosed within a large, loopy oval shape.

Kaleb Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Davis, Kable

From: Hollis, Angela
Sent: Thursday, December 15, 2016 1:23 PM
To: Davis, Kable
Subject: Forward about notification you asked about
Attachments: removed.txt

Hi Bo,

You asked me to ask her about the intent of "system" and this was her response. I believe you still have the jacket, so let me know if it's ok.

Thanks,
-Ang

From: [REDACTED] [mailto:[REDACTED]]
Sent: Monday, December 05, 2016 4:39 PM
To: Hollis, Angela <Hollis.Angela@epa.gov>
Subject: Re: Regarding Reg#56783-1

Personal privacy information

Angela,

The product will be sold alone - not in combination with any other products or devices. So, I believe the use of "system" in the alternate product name(s) refers to the use directions of applying in a grid pattern.

Hope this helps. Please let me know if you need anything further.

Sharon M. Johnston
RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050
TEL: 636-942-2583
e-mail: Johnston@RegGuide.net
[REDACTED]

Personal privacy information

In a message dated 12/5/2016 3:24:48 P.M. Central Standard Time, Hollis.Angela@epa.gov writes:



Good afternoon Sharon,

I'm working on this ABN, and I need further clarification on your intent regarding adding alternate brand names with the word "system" in it.

Please advise,

Thanks so much,

Angela Hollis

U.S. Environmental Protection Agency

Office of Pesticide Programs

Registration Division 7505-P

Phone- 703 347-0216

RegGuide

October 12, 2016

Document Processing Desk (NOTIF)
Registration Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900; One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: Laura Bacon
Product Manager 4
Invertebrate-Vertebrate Branch 1

SUBJECT: Notification of Alternate Brand Name
Damminix; EPA Reg. No. 56783-1

Dear Ms. Bacon:

Enclosed, please find one marked copy of the above-subject label. The only change being made at this time is the addition of two alternate brand names – “Damminix Tick Control System” and “Damminix Tick Defense System”.

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston
Regulatory Consultant
Agent for EcoHealth, Inc.

Enclosures

cc: A. Ganak; EcoHealth

Sharon M. Johnston, Esq.
509 Tower Valley Drive
Hillsboro, MO 63050

Tel: 636-942-2583
Fax: 636-948-9720
e-mail: Johnston@RegGuide.net



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-1	2. EPA Product Manager Laura Bacon	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Damminix	PM# 04	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Notification of Alternate Brand Names per PR Notice 98-10.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt. 0.16 oz	No. per container 6-24		<input checked="" type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.96 - 3.84 oz		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed directly on package			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sharon M. Johnston	Title Regulatory Consultant	Telephone No. (Include Area Code) (636) 942-2583
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant	
4. Typed Name Sharon M. Johnston	5. Date October 12, 2016	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 9, 2015

Sharon M. Johnston
Regulatory Consultant for
Ecohealth, Inc.
56 Hawes St.
Brookline, MA 02446

Subject: CSF Notification per PRN 98-10 – Updating the company and active ingredient information to reflect the transfer of registration in addition to including an additional source of supply of the active ingredient on the alternate CSF.
Product Name: Damminix
EPA Registration Number: 56783-1
Application Date: June 23, 2015
Decision Number: 506313

Dear Ms. Johnston:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 06/23/2015
- Alternate CSF 1 dated 06/23/2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink, which appears to read "Jennifer Urbanski", is written over a horizontal line.

Jennifer Urbanski, Ph.D.
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

RegGuide

June 23, 2015

Document Processing Desk (NOTIF)
Registration Division (7504P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Jennifer Urbanski
Product Manager 4

SUBJECT: Submission of Notification Per PR Notice 98-10 -- Submission of UPDATED Basic and NEW Alternate #1 Confidential Statements of Formula - alternate source of active ingredient Damminix; EPA Reg. No. 56783-1

Dear Dr. Urbanski:


Enclosed, please find two originally signed updated basic and new Alternate #1 Confidential Statements of Formula for the above-subject product. We have also included a formulator's exemption statement as well as a copy of the current basic CSF to facilitate review.

The basic CSF has been revised to update the company address and the active ingredient information (supplier address and EPA Reg. No.) pursuant to the [REDACTED]

Alternate formulation #1 is being added to include an additional source of supply of the active ingredient.

If you have any questions or need additional information, please do not hesitate to contact me at (636) 942-2583.

Sincerely,


Sharon M. Johnston
Regulatory Consultant

Enclosures

cc: A. Ganak; EcoHealth

Sharon M. Johnston, Esq.
509 Tower Valley Drive
Hillsboro, MD 63050

Tel: 636-942-2583
Fax: 636-948-9720
e-mail: Johnston@RegGuide.net

Product ingredient source information may be entitled to confidential treatment



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-1	2. EPA Product Manager Jennifer Urbanski	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Damminix	PM# 4	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 56 Hawes St. Brookline, MA 02446 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

NOTIFICATION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT PER PR NOTICE 98-10

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input checked="" type="checkbox"/> Paper	
				Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.95 - 3.81 oz		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed directly on package			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Sharon M. Johnston		Title Regulatory Consultant		Telephone No. (Include Area Code) 630-942-2583	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Sharon M. Johnston		5. Date June 23, 2015			



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

EcoHealth, Inc.
56 Hawes St.
Brookline, MA 02446

EPA File Symbol/Registration Number

55783-1

Product Name

Damminix

Date of Confidential Statement of Formula (EPA Form 8570-4)

June 23, 2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Permethrin

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Permethrin		
Permethrin		

Product ingredient source information may be entitled to confidential treatment

Signature

Name and Title

Sharon M. Johnston / Regulatory Consultant

Date

June 23, 2015

Material Sent for Data Extraction

Reg. # 56783.1

Description: Ames

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 7-29-12

☐ Notification Dated _____

☒ New CSF(s) Dated 4-30-12

☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Eric Kuro

Phone: Division: RD 308-9358

Date: 7-29-12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Sharon Johnston
Agent for EcoHealth, Inc.
509 Tower Valley Drive
Hillsboro, MO 63050

Subject: Amended Reregistration Label
Product Name: Damminix
EPA Registration Number: 56783-1

Dear Ms. Johnston:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the permethrin RED(s), and has concluded that your submission is acceptable.

NOTE: This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

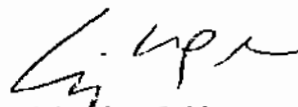
Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated 4-30-10

A copy of your label stamped "Accepted" is enclosed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact either Erik Kraft at (703-308-9358) or via email at Kraft.Erik@epa.gov or Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'R. Gebken', written over a horizontal line.

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

DAMMINIX®

A TICK TOXICANT

As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths and in woodlands.

24 tubes treats approximately 22,000 sq. ft.

Active Ingredient:

Permethrin* 7.4%

Other Ingredients: 92.6%

Total 100.00%

*Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

EPA Reg. No. 56783-1

EPA Est. No.

Keep Out of Reach of Children

CAUTION

First Aid

If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may call 1-800-222-1222 for emergency medical treatment information.

ACCEPTED
7 29-13
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under
EPA Reg. No. 56783-1

See side [back] panel for additional precautions.

EcoHealth, Inc.
56 Hawes Street
Brookline, MA 02446
(617) 742-2400

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed. The tubes and unused cotton are biodegradable and may be left in the application site.

Storage and Disposal

Do not contaminate water, food or feed by storage.

Storage: Store at room temperature in an area inaccessible to children and pets.

Disposal: If empty: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Net Contents:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

7-28-13

Sharon Johnston
509 Tower Valley Drive
Hillsboro, MO 63050

Subject: Request for Updated Reregistration Label for EPA Reg. No. 56783-1
Product Name: Dammix

Dear Ms. Johnston:

The Agency has completed a preliminary review of the label that your company submitted in support of the reregistration of EPA Reg. No. 56783-1 / Dammix and has determined that the referenced label did not effectively incorporate all mandatory mitigation language required by the permethrin RED(s).

Within 10 working days of the date of this letter, you must submit an updated label incorporating all mandatory mitigation language required by the RED(s) (please see the attached sheet for required changes). If we do not receive an amended label in response to this letter, the Agency may pursue further regulatory action, including cancellation under section 6 of FIFRA.

If you have any questions about this letter, please contact either Erik Kraft at (703-308-9358) or via email at Kraft.Erik@epa.gov or Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov. When submitting the amended label in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely yours,

A handwritten signature in black ink, appearing to read "R. Gebken".

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

The following changes must be incorporated into the label to be in compliance with the above mentioned RED(s):

1) Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

“Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.”

2) Revise the First Aid Statement so that the “If in Eyes” statement appears after the “If Swallowed” statement.

DAMMINIX®

A TICK TOXICANT

As an aid in the control of ticks (that may carry Lyme Disease) that infest mice and nests of mice found around yards, play areas, parks, brush, paths and in woodlands.

24 tubes treats approximately 22,000 sq. ft.

Active Ingredient:

Permethrin* 7.4%

Other Ingredients: 92.6%

Total 100.00%

*Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

EPA Reg. No. 56783-1

EPA Est. No.

Keep Out of Reach of Children

CAUTION

First Aid

If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may call 1-800-222-1222 for emergency medical treatment information.	

See side [back] panel for additional precautions.

EcoHealth, Inc.
33 Mt. Vernon St.
Boston, MA 02108
(617) 742-2400

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Avoid contact with eyes, skin or clothing. Contact with skin may result in temporary numbing and tingling sensations. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. The maximum distance between tubes should not exceed 10 yards in any direction. Treatment should be limited to areas inhabited by mice, and need not include mown lawns or open grasslands. Tubes should be positioned so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mown lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected should be treated.

FOR TREATMENT OF WOODLOTS: Tubes should be placed in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed. The tubes and unused cotton are biodegradable and may be left in the application site.

Storage and Disposal

Do not contaminate water, food or feed by storage.

Storage: Store at room temperature in an area inaccessible to children and pets.

Disposal: If empty: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Net Contents:

49081800

RegGuide

March 14, 2013

Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Bonnie Adler
Chemical Review Manager
Permethrin; Case No. 2510; PDCI-109701-26513

SUBJECT: EcoHealth, Inc.
Damminix®; EPA Reg. No. 56783-1
Mite Arrest®; EPA Reg. No. 56783-2
Submission of Storage Stability data Per Your Letter Dated January 11, 2013

Dear Ms. Adler:

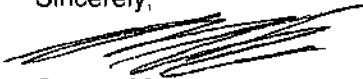
Enclosed, please find 14-day elevated temperature storage stability data in response to the Permethrin data call-in notice for the above-subject products. These products are identical in formulation.

A data matrix for each product is enclosed.

A transmittal document is attached as page 2 of this letter.

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston
Regulatory Consultant
Agent For EcoHealth, Inc.

Enclosures

cc: Ariana Ganak; EcoHealth

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

EcoHealth, Inc.
56 Hawes Street
Brookline, MA 02446

2. Regulatory Action in Support of Which This Package is Submitted

Application for Re-Registration

Damminix®; EPA Reg. No.: 56783-1
Mite Arrest®; EPA Reg. No. 56783-2

3. Transmittal Date

March 14, 2013

4. List of Submitted Studies:

<u>MRID No.</u>	<u>Volume No.</u>	<u>OPPTS Guideline No.</u>	<u>Study Title</u>
49081801	1 of 1	830.6317	Physical & Chemical Characteristics of Damminix® Tick Tubes: Storage Stability

Company Official: Sharon M. Johnston
Regulatory Consultant
Agent for EcoHealth, Inc.

Phone: (636) 942-2583

Signature: 

Company Name: EcoHealth, Inc.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-1	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Damminix	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 56 Hawes Street Brookline, MA 20446 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>01-11-2013</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Re-Registration - Submission of Storage Stability data

e-mail: Johnston@RegGuide.net

Fax: (636) 948-9720

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input checked="" type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt. 0.159 oz	No. per container 6 or 24		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.95 - 3.81 oz	5. Location of Label Directions <input checked="" type="checkbox"/> On label		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed directly on package			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sharon M. Johnston	Title Regulatory Consultant	Telephone No. (Include Area Code) (636) 942-2583	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant		
4. Typed Name Sharon M. Johnston	5. Date March 14, 2013		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 21, 2011

MEMORANDUM:

Subject: EPA Reg. No.: 56783-1 / Damminix
DP Barcode: 391063
Case No.: 2510

From: Jolene Trujillo, Biologist *Jolene Trujillo*
Risk Management and Implementation Branch V (7508P)
Pesticide Re-evaluation Division

To: Bonnie Adler, CRM
Risk Management and Implementation Branch V (7508P)
Pesticide Re-evaluation Division

Applicant: EcoHealth, Inc.
33 Mt. Vernon St.
Boston, MA 02108

FORMULATION FROM EPA Reg. No. 56783-1 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Permethrin	7.4%
<u>Other Ingredient(s):</u>	92.6%
Total	100.0%

BACKGROUND: In the 8 month response to the Permethrin RED, the registrant has cited acute toxicity studies to support the reregistration of their product, EPA Reg. No. 56783-1. The MRID's are as follows: 437997-01 (81-1), 437997-02 (81-2), 437997-03 (81-3), 478799-01 (81-4, waiver), 448338-01 (81-5), 438938-01 (81-6). Studies 81-1 and 81-2 were conducted by Biosearch Inc., 81-3 and 81-6 by Stillmeadow Inc., and 81-5 by AgrEvo UK Limited. The test material used in each of the studies was EPA Reg. No. 73049-277. These studies were previously reviewed by RMIBV/PRD on 06/22/10 and found acceptable.

The registrant provided a waiver request in MRID No. 478799-01 for primary eye irritation. Based on the use of the product and information presented in the waiver request, the Agency agrees that eye irritation exposure potential is minimal, though still possible, therefore a toxicity category III classification is expected to provide adequate protection.

RECOMMENDATIONS:

- The acute toxicity waiver and studies cited are acceptable to support the reregistration of EPA Reg. No. 56783-1.

The acute toxicity profile for EPA Reg. No. 56783-1 is currently:

Acute Oral	III	Cited
Acute Dermal	IV	Cited
Acute Inhalation	IV	Cited
Primary Eye	III	Cited
Primary Dermal	IV	Cited
Skin Sensitization	non sensitizer	Cited

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 56783-1 / Damminix

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

FIRST AID:

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA PACKAGE BEAN SHEET

Date: 23-Jul-2013

Page 1 of 1

Decision #: 413308

DP #: (413424)

NON PRIA

Parent DP #:

Submission #: 874710

E-Sub #:

*** Registration Information ***

Registration: 56783-1 - DAMMINIX

Company: 56783 - ECOHEALTH, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonnie Adler BADLER

Sent Date: 14-May-2010

PRIA Due Date: 05-May-2010

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (676) Product Reregistration Decision;

Ingredients: 109701, Permethrin(7.4%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 23-Jul-2013

Due Back:

DP Ingredient: 109701, Permethrin

DP Title: Final pkg for 56783-1 Permethrin

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date:

Team Name: RM 10

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

This permethrin product is recommended for final reregistration based on your review of the attached preliminary label assessment, along with PC and tox reviews for case 2510. The permethrin PDCL called in Efficacy for Impregnated Fabrics & ORMS as well as Companion Animal Safety data.

According to the Registrants Response form for this product:

Efficacy/Impregnated Fabrics [810.3300] were marked as "not applicable" (#8)

Efficacy/ORMS [810.3500] was marked as "not applicable" (#8).

Companion Animal Safety [870.7200] was marked as "not applicable" (#8)

Once you have made your decision, please put all pertinent information in the product jacket. Please contact Bonnie Adler with questions.

PRODUCT REREGISTRATION

SUPPORTING DOCUMENTATION

FOR

Case Name permethrin

Reg. No. 96733 1

This supporting documentation (in chronological order) includes:

- o Old labels (identified as "*Superseded by label dated*
xx/xx/xx")
- o Unacceptable CSF (marked "Not acceptable" and dated)
- o Product chemistry reviews
- o Acute toxicity reviews
- o Efficacy and or special studies (if necessary)
- o 90-Day responses to PDCI (forms A and B)
- o Administrative forms (Application for Reregistration
Certification to Data citation, Data Matrix)
- o Correspondence (Company and Agency letters & e-mails)

Date: July 19, 2013

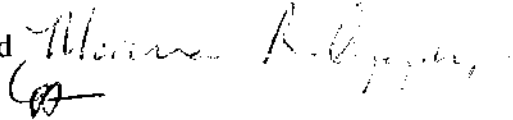
Reg. No.: 056783-001

Product Name: DAMMINIX

PM Name/Number: Richard Gebken, PM Team 10

Primary Reviewer: Moana R. Appleyard

Secondary Reviewer: Linda Arrington



New label or date of RD amended label: May 5, 2010

Active Ingredient(s) Assessed: Permethrin/109701

Formulation Type: Impregnated Materials

Other ai's in product

Name/PC code: NA

Reregistration Status or Registration Date: NA

Note to PM:

1) Although the Permethrin RED does not address Environmental Hazards Statement for impregnated material, the product is outdoor use only. Most outdoor use products carry an Environmental Hazard Statement. RMIBV defers to RD on this issue.

Assessment can be found N:\RMIBV\label\056783-001

1) Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

"Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."

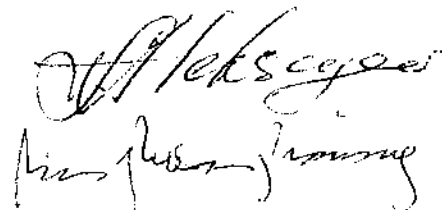
2) Revise the First Aid Statement so that the "If in Eyes" statement appears after the "If Swallowed" statement.

DATE OUT: 5/7/2013

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP []; EUP [X]

BARCODE NO.: 411211 REG./FILE SYMBOL NO.: 56783-1PRODUCT NAME: Damminix MRID NO: 490818-01COMPANY NAME: Ecohealth, Inc. ACTION CODE: 676

FROM: Sergey Alekseyev, Chemist
Product Chemistry Team
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)



TO: Bonnie Adler, CRM
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

INTRODUCTION:

With this resubmission, in response to our review dated 04/24/2012 (DP # 400463) the registrant provided additional product chemistry data pertaining to Storage Stability study (MRID No. 490818-01). The registrant is requesting reregistration of the product, Damminix, EPA Reg. No. 56783-1.

FINDINGS:

1. EPA Reg. No. 56783-1 is an end-use product containing the active ingredient Permethrin ((3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate), with a label claim nominal concentration of 7.4% and other ingredients content of 92.6%. The product is for use in controlling, ticks on lawns, flower gardens, under bushes etc. The product is produced by a non-integrated system.
2. As requested in Finding 4 of the previous review, an additional MRID has been submitted. Data reported in MRID No. 490818-01 satisfy the product chemistry data requirements under Subgroup B which pertains to Physical and Chemical Properties. In particular, said MRID states that the subject product is stable after 2 weeks at 54 °. Therefore, Guideline 830.6317 has been satisfied.
3. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2, 97-5, and 97-6. There are no data present that would trigger Physical or Chemical Hazards statements. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

Notice to PM: Storage and Disposal section should include Container Handling statements. PRD defers this issue to RD.

CONCLUSIONS:

The registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. 56783-1.

Administrative Materials




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date March 14, 2013			EPA Reg No./File Symbol 56783-1		Page 1 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446			Product Damminix		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	48085301	EcoHeath	OWN	
61-2/830.1600 & 830.1650	Beginning Materials & Manufacturing Process	48085301	EcoHeath	OWN	
61-3/830.1670	Discussion of Formation of Impurities	48085301	EcoHeath	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
62-2/830.1750	Certification of Ingredient Limits	48085301	EcoHeath	OWN	
62-3/830.1800	Analytical Method to Verify Certified Limits	48085301	EcoHeath	OWN	
63-2/830.6302	Color	164297	EcoHeath	OWN	
63-3/830.6303	Physical State	164297	EcoHeath	OWN	
63-4/830.6304	Odor	164297	EcoHeath	OWN	
63-5/830.7200	Melting Point				NA - EP
63-6/830.7220	Boiling Point				NA - EP
63-7/830.7300	Density, Bulk Density or Specific Gravity	164297	EcoHeath	OWN	
63-8/830.7840 & 830.7860	Solubility				NA - EP
63-9/830.7950	Vapor Pressure				NA - EP
63-10/830.7970	Dissociation Constant				NA - EP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 03-14-2013




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date March 14, 2013			EPA Reg No./File Symbol 56783-1		Page 2 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446			Product Damminix		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - EP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - EP
63-14/830.6314	Oxidizing/Reducing Actin				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	164297	EcoHealth	OWN	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6317	Storage Stability	Vol. 1 of 1	EcoHealth	OWN	
63-18/830.7100	Viscosity				NA - solid
63-19/830.6319	Miscibility				NA - not dilutable with petroleum solvents
63-20/830.6320	Corrosion Characteristics	48719801	EcoHealth	OWN	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	43799701	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	43799702	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43799703	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	47879901	EcoHealth	OWN	Waiver Request
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 03-14-2013



Date March 14, 2013		EPA Reg No./File Symbol 56783-1	Page 3 of 3
Applicant's/Registrant's Name & Address	EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446	Product	Damminix

[illegible]

Signature	Name and Title Sharon M. Johnston Regulatory Consultant	Date 03-14-2013
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date January 16, 2012			EPA Reg No./File Symbol 56783-1		Page 1 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108			Product Damminix		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	48085301	EcoHeath	OWN	
61-2/830.1600 & 830.1650	Beginning Materials & Manufacturing Process	48085301	EcoHeath	OWN	
61-3/830.1670	Discussion of Formation of Impurities	48085301	EcoHeath	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
62-2/830.1750	Certification of Ingredient Limits	48085301	EcoHeath	OWN	
62-3/830.1800	Analytical Method to Verify Certified Limits	48085301	EcoHeath	OWN	
63-2/830.6302	Color	164297	EcoHeath	OWN	
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63-4/830.6304	Odor	164297	EcoHeath	OWN	
63-5/830.7200	Melting Point				NA - EP
63-6/830.7220	Boiling Point				NA - EP
63-7/830.7300	Density, Bulk Density or Specific Gravity	164297	EcoHeath	OWN	
63-8/830.7840 & 830.7860	Solubility				NA - EP
63-9/830.7950	Vapor Pressure				NA - EP
63-10/830.7370	Dissociation Constant				NA - EP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 01-16-2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date January 16, 2012	EPA Reg No./File Symbol 56783-1	Page 2 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108	Product Damminix	

Ingredient Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - EP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - EP
63-14/830.6314	Oxidizing/Reducing Actin				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	164297	EcoHeath	OWN	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6317	Storage Stability	Vol. 1 of 2	EcoHeath	OWN	
63-18/830.7100	Viscosity				NA - solid
63-19/830.6319	Miscibility				NA - not dilutable with petroleum solvents
63-20/830.6320	Corrosion Characteristics	Vol. 1 of 2	EcoHealth	OWN	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	43799701	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	43799702	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43799703	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	47879901	EcoHealth	OWN	Waiver Request

Signature

Name and Title

Sharon M. Johnston
Regulatory Consultant

Date

01-16-2012



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-1	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Damminix	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Re-Registration - Submission of Storage Stability & Corrosion Characteristic data in response to the permethrin PDCI

e-mail: Johnston@RegGuide.net

Fax: (636) 948-9720

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input checked="" type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt. 0.159 oz	No. per container 6 or 24	If "Yes" Package wgt.	<input type="checkbox"/> Glass	
			No. per container	<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.95 - 3.81 oz		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other printed directly on package		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Sharon M. Johnston		Title Regulatory Consultant		Telephone No. (Include Area Code) (636) 942-2583	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Sharon M. Johnston		5. Date January 16, 2012			



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56783-1	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Damminix	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Re-Registration - 8-month response to the permethrin PDCI

e-mail: Johnston@RegGuide.net
Fax: (636) 948-9720

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.159 oz	No. per container 6 or 24	If "Yes" Package wgt	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.95 - 3.81 oz		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other printed directly on package		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sharon M. Johnston	Title Regulatory Consultant	Telephone No. (Include Area Code) (636) 942-2583	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant		
4. Typed Name Sharon M. Johnston	5. Date April 30, 2010		

480853-00

RegGuide

April 30, 2010

Product Reregistration Branch
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Bonnie Adler
Chemical Review Manager
Permethrin; Case No. 2510; PDCI-109701-26513

SUBJECT: **Permethrin** – 8-Month Response to Data Call-In Notice
EcoHealth, Inc.
Damminix®; EPA Reg. No. 56783-1

Dear Ms. Adler:

Enclosed, please find the 8-month response to the Permethrin data call-in notice for the above-subject product.

The following materials are enclosed:

- 1) Application for Registration
- 2) Formulators Exemption Statement
- 3) Confidential Statement of Formula
- 4) Certification with Respect to Citation of Data
- 5) Letter of Authorization from Valent BioSciences Corporation
- 6) Data Matrix
- 7) Draft Labeling (5 copies)
- 8) Data Volume 1 of 1 (3 copies)

A transmittal document is attached as page 2 of this letter.

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston
Regulatory Consultant
Agent For EcoHealth, Inc.

Enclosures

Cc: Ariana Ganak; EcoHealth

Sharon M. Johnston, Esq.
509 Tower Valley Drive
Hillsboro, MO 63050

Tel: 636-942-2583
Fax: 636-948-9720
e-mail: Johnston@RegGuide.net

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

EcoHealth, Inc.
33 Mt. Vernon St.
Boston, MA 02108

2. Regulatory Action in Support of Which This Package is Submitted

Application for Re-Registration

Damminix®; EPA Reg. No.: 56783-1

3. Transmittal Date

April 30, 2010

4. List of Submitted Studies:

<u>MRID No.</u>	<u>Volume No.</u>	<u>OPPTS Guideline No.</u>	<u>Study Title</u>
<u>48085301</u>	1 of 1	830.1550, 1600 1650, 1670, 1700, 1750 & 1800	Group A Product chemistry of Damminix (EPA Reg. No. 56783-1) & Mite Arrest (EPA Reg. No. 56789-2)

Company Official: Sharon M. Johnston
Regulatory Consultant
Agent for EcoHealth, Inc.

Phone: (636) 942-2583

Signature: 

Company Name: EcoHealth, Inc.




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date April 30, 2010			EPA Reg No./File Symbol 56783-2		Page 1 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108			Product Mite Arrest		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	56783-1	EcoHeath	OWN	
61-2/830.1600 & 830.1650	Beginning Materials & Manufacturing Process	56783-1	EcoHeath	OWN	
61-3/830.1670	Discussion of Formation of Impurities	56783-1	EcoHeath	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
62-2/830.1750	Certification of Ingredient Limits	56783-1	EcoHeath	OWN	
62-3/830.1800	Analytical Method to Verify Certified Limits	56783-1	EcoHeath	OWN	
63-2/830.6302	Color	164297	EcoHeath	OWN	
63-3/830.6303	Physical State	164297	EcoHeath	OWN	
63-4/830.6304	Odor	164297	EcoHeath	OWN	
63-5/830.7200	Melting Point				NA - EP
63-6/830.7220	Boiling Point				NA - EP
63-7/830.7300	Density, Bulk Density or Specific Gravity	164297	EcoHeath	OWN	
63-8/830.7840 & 830.7860	Solubility				NA - EP
63-9/830.7950	Vapor Pressure				NA - EP
63-10/830.7370	Dissociation Constant				NA - EP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 04-30-2010



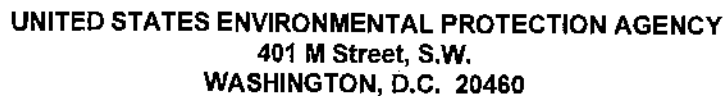
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DATA MATRIX

Date April 30, 2010			EPA Reg No./File Symbol 56783-2		Page 2 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108			Product Mite Arrest		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - EP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - EP
63-14/830.6314	Oxidizing/Reducing Actin				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	164297	EcoHealth	OWN	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6317	Storage Stability	On-going	EcoHealth	OWN	
63-18/830.7100	Viscosity				NA - solid
63-19/830.6319	Miscibility				NA - not compatible with petroleum solvents
63-20/830.6320	Corrosion Characteristics	On-going	EcoHealth	OWN	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	43799701	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	43799702	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43799703	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	47879901	EcoHealth	OWN	Waiver Request
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 04-30-2010



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Date April 30, 2010		EPA Reg No./File Symbol 56783-2	Page 3 of 3
Applicant's/Registrant's Name & Address	EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108	Product Mite Arrest	

[illegible]

Signature	Name and Title Sharon M. Johnston Regulatory Consultant	Date 04-30-2010
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DATA MATRIX

Date April 30, 2010			EPA Reg No./File Symbol 56783-1		Page 1 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108			Product Damminix		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	Vol. 1 of 1	EcoHeath	OWN	
61-2/830.1600 & 830.1650	Beginning Materials & Manufacturing Process	Vol. 1 of 1	EcoHeath	OWN	
61-3/830.1670	Discussion of Formation of Impurities	Vol. 1 of 1	EcoHeath	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
62-2/830.1750	Certification of Ingredient Limits	Vol. 1 of 1	EcoHeath	OWN	
62-3/830.1800	Analytical Method to Verify Certified Limits	Vol. 1 of 1	EcoHeath	OWN	
63-2/830.6302	Color	164297	EcoHeath	OWN	
63-3/830.6303	Physical State	164297	EcoHeath	OWN	
63-4/830.6304	Odor	164297	EcoHeath	OWN	
63-5/830.7200	Melting Point				NA - EP
63-6/830.7220	Boiling Point				NA - EP
63-7/830.7300	Density, Bulk Density or Specific Gravity	164297	EcoHeath	OWN	
63-8/830.7840 & 830.7860	Solubility				NA - EP
63-9/830.7950	Vapor Pressure				NA - EP
63-10/830.7370	Dissociation Constant				NA - EP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 04-30-2010



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DATA MATRIX

Date April 30, 2010		EPA Reg No./File Symbol 56783-1		Page 2 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108		Product Damminix			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - EP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - EP
63-14/830.6314	Oxidizing/Reducing Actin				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	164297	EcoHealth	OWN	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6317	Storage Stability	On-going	EcoHealth	OWN	
63-18/830.7100	Viscosity				NA - solid
63-19/830.6319	Miscibility				NA - not dilutable with petroleum solvents
63-20/830.6320	Corrosion Characteristics	On-going	EcoHealth	OWN	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	43799701	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	43799702	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43799703	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	47879901	EcoHealth	OWN	Waiver Request
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 04-30-2010



Date	April 30, 2010	EPA Reg No./File Symbol	56783-1	Page 3 of 3
Applicant's/Registrant's Name & Address	EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108	Product	Damminix	

[illegible]

Signature	Name and Title	Date
	Sharon M. Johnston Regulatory Consultant	04-30-2010

RegGuide

September 28, 2009

Product Reregistration Branch
Special Review & Reregistration Division (7508P)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: Bonnie Adler
Chemical Review Manager
Permethrin; Case No. 2510; PDCI-109701-26513

SUBJECT: **Permethrin** - 90-Day Response to Data Call-In Notice
EcoHealth, Inc.; EPA Co. No. 56783

Dear Ms. Adler:

Enclosed, please find the 90-day response to the Permethrin data call-in notice on behalf of EcoHealth, Inc.:

The following materials are enclosed:

- 1) Product Specific Data Call-In Response form
- 2) Product Specific Requirements Status and Registrant's Response
- 3) Waiver Request for Primary Eye Irritation study (3 copies)

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston
Regulatory Consultant
Authorized Agent for EcoHealth, Inc.

Enclosures

cc: Ariana Ganak; EcoHealth

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

EcoHealth, Inc.
33 Mount Vernon Street
Boston, MA 02108

2. Regulatory Action in Support of Which This Package is Submitted

Application for Re-registration

Damminix; EPA Reg. No.: 56783-1
Mite Arrest; EPA Reg. No.: 56783-2

3. Transmittal Date

September 28, 2009

4. List of Submitted Studies:

<u>MRID No.</u>	<u>Volume No.</u>	<u>OPPTS Guideline No.</u>	<u>Study Title</u>
<u>47879901</u>	1 of 1	870.2400	Request for Waiver of Primary Eye Irritation Study Based on the Physical Properties of Damminix; EPA Reg. no. 56783-1 Mite Arrest; EPA Reg. No. 56783-2

Company Official: Sharon M. Johnston
Authorized Agent for EcoHealth, Inc.

Phone: (636) 942-2583

Signature: 

Company Name: EcoHealth, Inc.

ECOHEALTH, INC.

September 9, 2009

Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (7508P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

SUBJECT: EcoHealth, Inc.; EPA Co. No. 56783
Authorization of Company Representative

Dear Sir/Madam:

EcoHealth, Inc., 33 Mt. Vernon St., Boston, MA 02108 hereby authorizes Sharon M. Johnston of RegGuide, 509 Tower Valley Drive, Hillsboro, Missouri 63050, to act on behalf of EcoHealth, Inc. as an authorized company representative for following regulatory action(s) ONLY:

The response to and follow-up with the US Environmental Protection Agency regarding the Data Call-In Notice for Permethrin.

This authorization may be revoked at any time upon written notice. Please contact me at (617) 742-2400 if you have any questions or need additional information.

Sincerely,



Ariana Ganak, Director
EcoHealth Inc.

cc: Sharon M. Johnston; RegGuide

United States

Washington, DC 20460

Formulator's Exemption Statement (40 CFR 152.85)

(40 CFR 152.85)

Applicant's Name and Address

EcoHealth, Inc.
33 Mt. Vernon St.
Boston, MA 02108

EPA File Symbol/Registration Number

56783-1

Product Name

Damminix

Date of Confidential Statement of Formula (EPA Form 8570-4)

April 30, 2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Permethrin

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

- (3) Indicate by checking (A) or (B) below which paragraph applies:


- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☒ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Permethrin	[REDACTED]	[REDACTED]
<i>*Product ingredient source information may be entitled to confidential treatment*</i>		
Signature 	Name and Title Sharon M. Johnston / Regulatory Consultant	Date April 30, 2010



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number EcoHealth, Inc., 33 Mt. Vernon St., Boston, MA 02108 TEL: (636) 942-2583	EPA Registration Number/File Symbol 56783-1
Active Ingredient(s) and/or representative test compound(s) Permethrin	Date April 30, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Non-Food, Domestic Outdoor	Product Name Damminix

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☒ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 04-30-2010	Typed or Printed Name and Title Sharon M. Johnston / Regulatory Consultant
---------------	--------------------	---

✓ 10/16/09

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

DATA CALL-IN RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address ECOHEALTH, INC. 33 MT. VERNON ST. BOSTON, MA 02108	2. Case # and Name 2510 Permethrin Chemical # and Name 109701 Permethrin	3. Date and Type of DCI and Number 28-May-2009 PRODUCT SPECIFIC ID # PDCI-109701-26513
---	---	---

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
56783-1 56783-2		N.A. N.A.	N.A. N.A.		yes yes

8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative  Regulatory Consultant

9. Date

9-28-09

10. Name of Company Eco Health, Inc.

11. Phone Number 636-942-2583

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address ECOHEALTH, INC. 33 MT. VERNON ST. BOSTON, MA 02108		2. Case # and Name 2510 Permethrin EPA Reg. No. 56783-1			3. Date and Type of DCI and Number 28-May-2009 PRODUCT SPECIFIC ID # PDCI-109701-26513				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	<u>Product Chemistry Data Requirements (Conventional Chemical)</u>								
830.1550	Product identity and composition (32)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.1600	Description of materials used to produce the product (33)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.1620	Description of production process (34)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	8
830.1650	Description of formulation process (35)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	1
830.1670	Discussion of formation of impurities (36)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.1700	Preliminary analysis (26, 27, 37)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	8
830.1750	Certified limits (38)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.1800	Enforcement analytical method (39)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.6302	Color (12)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.6303	Physical state (25)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.6304	Odor (21)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law							11. Date		
Signature and Title of Company's Authorized Representative <i>[Signature]</i> Regulatory Consultant							4-28-09		
12. Name of Company EcoHealth, Inc.							13. Phone Number 636-942-2583		

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address ECOHEALTH, INC. 33 MT. VERNON ST. BOSTON, MA 02108		2. Case # and Name 2510 Permethrin EPA Reg. No. 56783-1		3. Date and Type of DCI and Number 28-May-2009 PRODUCT SPECIFIC ID # PDCI-109701-26513					
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.6313	Stability to sunlight, normal and elevated temperatures, metals, and metal ions (28, 29, 40)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	✓
830.6314	Oxidizing or reducing action (22)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.6315	Flammability (17)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.6316	Explosibility (16)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.6317	Storage stability of product (41)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	16	1
830.6319	Miscibility (20)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.6320	Corrosion characteristics (42)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	16	1
830.6321	Dielectric breakdown voltage (15)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.7000	pH of water solutions or suspensions (23, 24)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	✓
830.7050	UV/Visible absorption					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	✓
830.7100	Viscosity (30)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.7200	Melting point/melting range (18, 19)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	✓
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United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address ECOHEALTH, INC. 33 MT. VERNON ST. BOSTON, MA 02108		2. Case # and Name 2510 Permethrin EPA Reg. No. 58783-1			3. Date and Type of DCI and Number 28-May-2009 PRODUCT SPECIFIC ID # PDCI-109701-26513				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.7220	Boiling point/boiling range (10,11)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	8
830.7300	Density/relative density (13,14)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.7370	Dissociation constant in water (47,48)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	8
830.7550	Partition coefficient (n-octanol/water), shake flask method (49)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	8
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography (54)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	8
830.7840	Water solubility: Column elution method, shake flask method (50)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	8
830.7860	Water solubility, generator column method (51)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	8
330.7950	Vapor pressure (52,53)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	8
<u>Toxicology Data Requirements (Conventional Chemical)</u>									
870.1100	Acute Oral Toxicity (1,43)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI,EP,dilute EP?	8	6
870.1200	Acute dermal toxicity (2,3,44)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI,EP,dilute EP?	8	6
870.1300	Acute inhalation toxicity (4)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	6

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REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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1. Company Name and Address

ECOHEALTH, INC.
33 MT. VERNON ST.
BOSTON, MA 02108

2. Case # and Name

2510 Permethrin

EPA Reg. No. 56783-1

3. Date and Type of DCI and Number

28-May-2009

PRODUCT SPECIFIC

ID # PDCI-109701-26513

4. Guideline
Requirement
Number

5. Study Title

P
R
O
T
O
C
O
L

Progress
Reports

1 2 3

6. Use
Pattern

7. Test
Substance

8. Time
Frame
(Months)

9. Registrant
Response

870.2400

Acute eye irritation (5)

A, B, C, D, E, F, G, H, I,
J, K, L, M, N, O

TGAI & EP

8

7

870.2500

Acute dermal irritation (6,7)

A, B, C, D, E, F, G, H, I,
J, K, L, M, N, O

TGAI & EP

8

6

870.2800

Skin sensitization (8,9)

A, B, C, D, E, F, G, H, I,
J, K, L, M, N, O

TGAI & EP

8

6

870.7200

Companion animal safety (31)

A, B, C, D, E, F, G, H, I,
J, K, L, M, N, O

CHOICE

8

8

810.3300

Treatments to control pests of humans and pets (45)

A, B, C, D, E, F, G, H, I,
J, K, L, M, N, O

EP

8

8

810.3500

Premises treatments (46)

A, B, C, D, E, F, G, H, I,
J, K, L, M, N, O

EP

8

8

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